UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	No. 23 C 3568 MDL No. 3079 Judge Thomas M. Durkin

MEMORANDUM OPINION AND ORDER

Presently before the Court is multidistrict litigation arising out of hearing-related injuries allegedly caused by the use of the drug TEPEZZA®. Defendant Horizon Therapeutics USA, Inc. filed four motions to dismiss the bellwether discovery cases. The Court granted one of those motions and dismissed Plaintiff Merriweather's complaint on choice-of-law grounds. Plaintiff Kanesta-Rychner also filed a motion for leave to amend her complaint. For the following reasons, the motion to dismiss the failure-to-warn claims is denied; the motion to dismiss the design defect claims is granted; the motion to dismiss the fraudulent misrepresentation claims is granted in part, denied in part, and continued in part; and Kanesta-Rychner's motion for leave to file a second amended complaint is denied.

Background

I. Overview

Thyroid eye disease ("TED") is a condition characterized by inflammation of the tissue around the eyes. *Chryssos v. Horizon Therapeutics USA, Inc.*, No. 1:23-cv-

03033 (N.D. Ill. Feb. 29, 2024), ECF No. 12 ¶ 28.[1] Symptoms can vary greatly from one person to another, and range from mild to severe. *Id.* ¶ 31. The most noticeable symptom is exophthalmos or proptosis, which refers to the bulging or protrusion of the eyes out of the eye socket. *Id.* Other symptoms include redness, irritation, discomfort, eyelid retraction or swelling, blurred or double vision, chronic bloody eyes, watery eyes, intolerance to bright lights, and difficulty moving the eyeballs. *Id.*

TEPEZZA® or teprotumumab ("Tepezza") is a medication used to treat TED. *Id.* ¶ 42. Tepezza acts by inhibiting the activity of the protein insulin-like growth factor-1 receptor ("IGF-1R"). *Id.* ¶¶ 46, 103. The FDA granted Tepezza "Orphan Drug" designation in 2013, "Fast Track" designation in 2015, and "Breakthrough" designation in 2016. *Id.* ¶¶ 37–40. Defendant Horizon Therapeutics USA, Inc. ("Horizon"), the pharmaceutical company involved in the manufacture, research, development, marketing, distribution, and sale of Tepezza, submitted the Biologic License Application ("BLA") for the drug in July 2019. *Id.* ¶¶ 19–20. In January 2020, the FDA approved Tepezza, making it the first approved drug indicated to treat TED. *Id.* ¶ 42.

The plaintiffs in this action were prescribed Tepezza to treat their TED, and received the drug through a series of intravenous infusions. *Id.* ¶ 10. They allege that Tepezza caused them to suffer permanent hearing loss and/or tinnitus. *Id.* ¶¶ 11, 12. They claim that Horizon failed to adequately warn physicians and consumers about

[1] The parties cite to Plaintiff Chryssos' First Amended Complaint ("FAC"), which is representative of the FACs of all bellwether discovery plaintiffs. The Court adopts the same approach and cites the complaint as "FAC."

the risks of hearing-related injuries, that Tepezza was defectively designed, and that Horizon fraudulently misrepresented the safety and efficacy of Tepezza.

II. Label

FDA regulations set forth the required content and format of labeling for prescription drug and biologic products. The sections of the label include but are not limited to: Highlights of Prescribing Information; Warnings and Precautions (Section 5); Adverse Reactions (Section 6); Patient Counseling Information (Section 17). At a high level, the Warnings and Precautions section describes "clinically significant adverse reactions," while the Adverse Reactions section describes "the overall adverse reaction profile of the drug." 21 C.F.R. § 201.57(6), (7). An adverse reaction is "an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." 21 C.F.R. § 201.57(7). The Adverse Reactions section contains subsections for Clinical Trials Experience, which lists the adverse reactions that are identified in clinical trials, and Postmarketing Experience, which lists adverse reactions that are identified from "domestic and foreign spontaneous reports." *Id.*

At its approval in January 2020, Tepezza's label included two references to hearing impairment:

- Within the Adverse Reactions section, the Clinical Trials Experience subsection noted that 10% of participants in two clinical studies experienced "[h]earing impairment (includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis[2] and autophony)."

[2] Hyperacusis is defined as abnormally acute hearing, while hypoacusis is defined as the partial loss of hearing. *Hyperacusis*, Merriam-Webster Dictionary,

- Within the Highlights of Prescribing Information section, the Adverse Reactions subsection listed "hearing impairment" as one of the "[m]ost common adverse reactions (incidence greater than 5%)."

FAC ¶¶ 52, 67, 267; R. 178-2. On January 20, 2023, Horizon submitted a supplemental BLA, proposing the following additions to the label:

- Within the Warnings and Precautions section, that Tepezza may cause "transient, or rarely permanent, hearing impairment or loss" based upon "post marketing reports received of cases with a higher level of severity compared to cases from clinical trial experience."

- Within the Adverse Reactions section, "hearing impairment" to the introductory language, tinnitus to the Clinical Trials Experience subsection; and severe hearing impairment or loss to the Postmarketing Experience subsection.

- Within the Patient Counseling Information section, "advise patients that [Tepezza] may cause transient or, rarely, permanent hearing impairment or loss."

FAC ¶¶ 118–19. In July 2023, the FDA approved a new label, adding:

- Within the Warnings and Precautions section, a subsection titled "Hearing Impairment Including Hearing Loss," which states that Tepezza "may cause severe hearing impairment including hearing loss, which in some cases may be permanent" and an instruction to assess patients' hearing "before, during, and after treatment with" Tepezza and "consider the benefit-risk of treatment."

- Within the Adverse Reactions section, "Hearing Impairment Including Hearing Loss" and in the Postmarketing Experience subsection, "Otologic: severe hearing impairment including hearing loss, which in some cases may be permanent."

- Within the Patient Counseling Information section, "Advise patients that [Tepezza] may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Instruct patients to contact their healthcare provider if they experience any signs or symptoms of hearing impairment or any changes in hearing."

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https://www.merriam-webster.com/medical/hyperacusis; *Hypoacusis*, Merriam-Webster Dictionary, https://www.merriam-webster.com/medical/hypoacusis.

- Within the Highlights of Prescribing Information, "Hearing Impairment Including Hearing Loss" under "Recent Major Changes" and the new language under "Warnings and Precautions."

Id. ¶ 140; R. 178-4. Additionally, within the Clinical Trials Experience subsection of the Adverse Reactions section, the description of hearing-related adverse reactions now reads, "Hearing impairment including hearing loss (deafness, including sensorineural deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, autophony and tinnitus)." R. 178-4.

III. Procedural History

In June 2023, the Judicial Panel on Multidistrict Litigation centralized numerous cases into the *Tepezza* MDL. On November 3, 2023, the Court dismissed plaintiff Cynthia Williams' post-approval design defect claims as preempted but allowed her pre-approval design defect claims to proceed. R. 70. The parties subsequently selected twelve cases as bellwethers to proceed to dispositive motion practice and discovery, which are summarized in the following chart:

Plaintiff	**State of Injury**	**Final Infusion Date**	**Claims**
Brooke Bounds	Florida	4/3/2023	failure to warn (strict liability and negligent) design defect (strict liability and negligent)
Peter Chryssos	New York	9/30/2022	failure to warn (strict liability and negligent) design defect (strict liability and negligent) fraudulent misrepresentation
Consuelo Egger	California	8/31/2022	failure to warn (strict liability and negligent) design defect (negligent only) fraudulent misrepresentation
Joseph Ford	Pennsylvania	10/31/2021	failure to warn (negligent only) design defect (negligent only) fraudulent misrepresentation
Geri Kanesta-Rychner	Washington	9/28/2022	failure to warn (strict liability only)
Sara Meilleur	Tennessee	12/31/2022	failure to warn (strict liability and negligent) design defect (strict liability and negligent)
Cherl Merriweather	Michigan	5/31/2023	failure to warn (strict liability and negligent) design defect (strict liability and negligent)

Rebecka Meyers	Utah	9/30/2020	failure to warn (strict liability and negligent) design defect (negligent only) fraudulent misrepresentation
Sara Perkett	Florida	9/19/2022	failure to warn (strict liability and negligent) design defect (strict liability and negligent)
Gloria Pledger	Maryland	12/31/2021	failure to warn (strict liability and negligent) design defect (negligent only)[3]
Amarilis Polanco	New Jersey	5/31/2022	failure to warn (strict liability and negligent) design defect (strict liability and negligent)
Richard Stern	New York	10/31/2021	failure to warn (strict liability and negligent) design defect (strict liability and negligent) fraudulent misrepresentation

Horizon has since moved to dismiss: (1) the failure to warn claims asserted by the plaintiffs who were treated with Tepezza before September 30, 2022 as preempted; (2) all design defect claims as inadequately pled; (3) all fraudulent misrepresentation claims as preempted and for failure to plead with particularity; and (4) all claims asserted by Merriweather on choice-of-law grounds. The Court granted the motion to dismiss Merriweather's complaint. R. 246. Eleven bellwether discovery cases remain ("Plaintiffs"), and the other three motions are pending before the Court. Also pending is Kanesta-Rychner's motion for leave to file a second amended complaint to add claims for negligent failure to warn and negligent design defect that she inadvertently omitted from her first amended complaint.

Discussion

Horizon moves to dismiss the failure-to-warn, design defect, and fraudulent misrepresentation claims across the remaining eleven bellwether discovery cases,

[3] Pledger initially alleged a strict liability design defect claim but conceded that claim in response to Horizon's motion to dismiss. *See* R. 198 at 24–25.

and Kanesta-Rychner moves for leave to file a second amended complaint. The Court addresses each motion in turn. [4]

I. Failure to Warn

All Plaintiffs bring failure-to-warn claims under the applicable state laws. Horizon contends that the failure-to-warn claims asserted by the nine plaintiffs who completed their treatment before September 30, 2022 are preempted.

A. Law on Preemption

Preemption occurs "when it is 'impossible for a private party to comply with both state and federal requirements.'" *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 303 (2019) (quoting *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 480 (2013)). Here, the state requirements include state common law and state statutes that require biologic drug manufacturers to warn consumers of the risks associated with the drugs, while the federal requirement is the statutory and regulatory scheme through which the FDA regulates the information that appears on drug labels. *Id.* Preemption is a question of law. *Id.* at 318.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), pharmaceutical companies may not manufacture a new biologic unless the FDA has approved a BLA. The BLA must demonstrate that the biologic is safe and propose a label. 21 U.S.C. § 355(b); 42 U.S.C. § 262(a); 21 C.F.R. § 601.2(a). As described in greater detail in the

[4] Horizon requests that the Court take judicial notice of various publicly available documents and court filings in considering its motions to dismiss. R. 179, 182, 185. Plaintiffs have not raised any opposition to those requests. The Court considers the documents and filings to the extent cited in this opinion. *See Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013).

background section, FDA regulations set forth the content and format of labeling for a biologic, which includes sections for Warnings and Precautions (Section 5), Adverse Reactions (Section 6), and Patient Counseling Information (Section 17). *See* 21 C.F.R. § 201.57. The FDA reviews the proposed label to determine if it is "false or misleading." 21 C.F.R. §§ 201.56, 201.57. Once the BLA is approved, the manufacturer must distribute the drug with the FDA-approved label. "Otherwise, the drug is misbranded and may not be distributed in the United States." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 806 (7th Cir. 2018).

Yet, the FDCA and FDA regulations also recognize that information about a drug's safety may change over time, and new information may warrant changes to the label. *Albrecht*, 587 U.S. at 304; *Wyeth v. Levine*, 555 U.S. 555, 567 (2009). There are two ways for a manufacturer to change a label without violating federal law. First, a manufacturer can seek advanced permission from the FDA to change the label. *Albrecht*, 587 U.S. at 304; *Wyeth*, 555 U.S. at 568. "This is the default rule for most substantive changes to drug labels." *Dolin*, 901 F.3d at 806. Second, a manufacturer can change the label without prior FDA approval under the "changes being effected" or CBE regulation. The CBE regulation allows a manufacturer to change a label to "reflect newly acquired information" if the changes "add or strengthen . . . a warning, precaution, or adverse reaction" for which the "evidence of a causal association satisfies the standard for inclusion in the labeling" found elsewhere in the regulations. 21 C.F.R. § 601.12(f)(2)(i)(A). The FDA retains the authority to reject

labeling changes made pursuant to the CBE regulation and force manufacturers to revert to the prior version of the label. *Dolin*, 901 F.3d at 812.

Therefore, a plaintiff's failure-to-warn claims are preempted if (1) the CBE process was not available, and thus the manufacturer could not unilaterally change the label, or (2) the manufacturer establishes by clear evidence that the FDA would have rejected the changes a plaintiff contends should have been made. *Id.* At the motion to dismiss stage, a plaintiff must allege "a labeling deficiency that [the manufacturer] could have corrected using the CBE regulation." *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 42 (1st Cir. 2015). Put differently, a plaintiff must plead that the manufacturer had newly acquired information that showed a causal association between the drug and an effect that warranted a new or stronger warning, precaution, or adverse reaction in the label. *See Dolin*, 901 F.3d at 806.

B. Application

Plaintiffs' overarching claim is that Tepezza's label failed to adequately warn providers and consumers about the risk of hearing-related issues. More specifically, Plaintiffs allege the label was deficient in how it reflected: (1) the prevalence of the risk, i.e., the incidence rate; (2) the severity of the risk, i.e., severe or permanent hearing loss; (3) the type of the risk, i.e., tinnitus; and (4) the recommendation for audiological monitoring. *See, e.g.*, FAC ¶¶ 197, 211(a)–(o). Horizon argues the failure-to-warn claims are preempted because Plaintiffs do not adequately plead that

Horizon could have used the CBE process to unilaterally correct these deficiencies before September 30, 2022.

As previously discussed, the CBE process allows Horizon to add or strengthen a warning, precaution, or adverse reaction on a label without advance permission from the FDA, but only if there is newly acquired information ("NAI") that satisfies the operative causal standard between a drug and an adverse event. The FDA defines NAI as:

> [D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 601.12(f)(6).[5] Additionally, there are different causal standards depending on which section of the label is changed. To make a change in the Warnings and Precautions section (Section 5), there must be "reasonable evidence of a causal association" between a "clinically significant hazard" and the drug, but a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6). To make a change in the Adverse Reactions section (Section 6), there must be "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).[6] As described in the background section,

[5] The parties agree that the CBE regulations for pharmaceuticals (21 C.F.R. §§ 314.3, 314.70) and for biologic products (21 C.F.R. §§ 601.12(f)(2), (6)) are substantively identical. *See* R. 274 at 7.

[6] *See also* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49604 (Aug. 22, 2008) ("A

Tepezza's label as of January 2020 noted a 10% incidence rate of "[h]earing impairment (includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis and autophony)" observed in the two clinical trials within the Clinical Trials Experience subsection of the Adverse Reactions section.

Essentially, the Court's task is to identify a date at which Plaintiffs have plausibly alleged that Horizon had NAI that met the operative casual standard, such that Horizon could have used the CBE process to change the label. The nine Plaintiffs to whom this motion applies received Tepezza infusions at various periods between April 2020 and September 2022. For any one Plaintiff to avoid preemption of his or her failure-to-warn claim, Horizon must have been able to change the label before that Plaintiff concluded his or her treatment with Tepezza. *See Sabol v. Bayer Healthcare Pharm., Inc.*, 439 F. Supp. 3d 131, 148 n.13 (S.D.N.Y. 2020) (articles published after exposure have "no bearing on her failure-to-warn claim."); *see also Ridings v. Maurice*, 444 F. Supp. 3d 973, 993 (W.D. Mo. 2020). Plaintiffs contend that there was sufficient information to justify revising the label as of September 2020, before any of the Plaintiffs had completed his or her treatment, while Horizon maintains that there was no such information until after September 30, 2022.

The Court begins with the information available as of September 2020: (1) the Extended Access Program Study ("Study 401") reporting a 40% incidence rate of

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CBE submission may be made when the evidence meets the standard set forth in this rule, even if that evidence would not also support a higher evidentiary standard, such as a finding that there is a preponderance of evidence that a product actually causes a particular kind of adverse event.").

hearing impairment; (2) an article by Victor D. Liou and Michael K. Yoon noting a 12% incidence rate in one of the clinical trials; (3) American Speech-Language-Hearing Association ("ASHA") 2020 guidelines recommending baseline audiology testing for ototoxic medications; and (4) 25 adverse event reports of deafness, hypoacusis, and tinnitus from Tepezza users.

Study 401, on its own, is sufficient to plead that a deficiency that Horizon could have fixed through the CBE process as of September 2020. First, Study 401 plausibly reflects a risk of greater frequency than previously submitted to the FDA. The study, which was last updated on March 16, 2020, reported a 40% incidence rate of hearing impairment. FAC ¶¶ 120, 263.[7] That incidence rate significantly exceeds the 10% incidence rate reported on the label, which came from the two clinical trials that Horizon shared with the FDA when seeking initial approval. *Id.* ¶ 67. Additionally, the Study 401 results were not reported on ClinicalTrials.gov, and there is no allegation the FDA otherwise had access to them. *Id.* ¶¶ 69, 120. In short, Plaintiffs allege the existence of a new clinical study that was not previously submitted to the FDA that indicated a risk of hearing impairment at a greater frequency than previously reported. *Cf. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019) (dismissing failure to warn claims as preempted where the complaint gave

[7] As of the date of the amended complaint, Study 401 was last updated on March 16, 2020. A review of the webpage for Study 401 on ClinicalTrials.gov shows further updates on June 18, 2024. *See Expanded Access Protocol of Teprotumamab (HZN-001) for Patients With Active Thyroid Eye Disease (EAP)*, (NCT04040894) (available at https://clinicaltrials.gov/study/NCT04040894?intr=teprotumamab&rank=3) (last accessed November 19, 2024).

no basis from which the court could conclude that the bleeding events covered by the alleged "reports" and "studies" were more severe or more frequent than bleeding events that the FDA already knew about).

Second, Study 401 satisfies the causal standard necessary for a label change. Study 401 plausibly shows "some basis to believe" there is a causal association between Tepezza and hearing impairment. As alleged, the Clinical Trials Experience subsection within the Adverse Reactions section identified "hearing impairment" as an adverse reaction observed in two clinical trials. In other words, the 10% incidence rate observed in the two original clinical trials constituted "some basis to believe" there was a causal relationship between Tepezza and hearing impairment. 21 C.F.R. § 201.57. In combination with the clinical trial data, the 40% incidence rate observed in Study 401 plausibly provides at least "some basis to believe" that Tepezza causes hearing impairment at a higher rate than indicated in the trials, thus warranting new or stronger language in the Adverse Reactions section.

Horizon argues that Study 401 does not plausibly indicate a risk of greater frequency because it was not as rigorous as a clinical trial. The CBE regulation expressly defines NAI to include "clinical studies," not just clinical trials. 21 C.F.R. § 601.12(f)(6). Further, Horizon's criticism of the quality of Study 401 goes to the sufficiency of the evidence proving the allegations, not the sufficiency of the allegations. Under the pleading standard, drawing all reasonable inferences in Plaintiffs' favor, Study 401 plausibly suggests a higher frequency of hearing impairment than what was previously reported to the FDA.

Horizon also argues that there was no label change to be made because the Adverse Reactions section already identified "hearing impairment" as an adverse reaction. But the CBE regulation permits label changes to "add or *strengthen* . . . a warning, precaution, or adverse reaction." 21 C.F.R. § 601.12(f)(2)(i)(A) (emphasis added). The difference between 10% and 40% is not trivial. FDA regulations did not bar Horizon from strengthening the Adverse Reactions section to reflect the higher frequency of hearing impairment observed in Study 401 than in the clinical trials. Accordingly, Plaintiffs adequately plead that Horizon could have changed the label to reflect a greater prevalence of the risk of hearing-related events as of September 2020.

On that basis, Plaintiffs' failure-to-warn claims avoid preemption at this stage. The Court declines to address whether Plaintiffs adequately plead sufficient information triggering Horizon's ability to fix other alleged deficiencies in the label, namely the type of risk (tinnitus), the severity of the risk (permanent hearing impairment), and the recommendation of audiological monitoring. Plaintiffs note the discovery produced to date would allow them to strengthen their allegations related to NAI. For example, Plaintiffs represent that Horizon's internal review of its clinical trial data in February 2021 showed "dozens of cases of unresolved hearing loss dating back to 2014." R. 199 at 16. Relatedly, defense counsel suggests that Horizon gave the FDA the results of Study 401 in 2021. Tr. 22; R. 214 at 7 n.16. It is telling that district courts overwhelmingly conduct the preemption analysis at the summary judgment stage, with the benefit of discovery. The Court's task, at this stage, is to

apply the pleading standard. Under that standard, where the Court draws all reasonable inferences in Plaintiffs' favor, the allegations are sufficient to avoid preemption. But the conclusion may be different after discovery is completed. The motion to dismiss the nine bellwether discovery Plaintiffs' failure-to-warn claims is denied.

II. Design Defect

All Plaintiffs except Kanesta-Rychner assert design defect claims under the applicable state laws. Horizon moves to dismiss for failure to state a claim.

A. Legal Standard

A Rule 12(b)(6) motion challenges the "sufficiency of the complaint." *Berger v. Nat. Collegiate Athletic Assoc.*, 843 F.3d 285, 289 (7th Cir. 2016). A complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), sufficient to provide defendant with "fair notice" of the claim and the basis for it. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). This standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While "detailed factual allegations" are not required, "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. The complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "Facial plausibility exists 'when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for

the misconduct alleged.'" *Thomas v. Neenah Joint Sch. Dist.*, 74 F.4th 521, 523 (7th Cir. 2023) (quoting *Iqbal*, 556 U.S. at 678). In applying this standard, the Court accepts all well-pleaded facts as true and draws all reasonable inferences in favor of the non-moving party. *See Hernandez v. Ill. Inst. of Tech.*, 63 F.4th 661, 666 (7th Cir. 2023).

B. Application

Here, Plaintiffs allege that Tepezza's design is defective in a conclusory, boilerplate fashion. *E.g.*, FAC ¶ 232 (Tepezza "was defective in design or formulation because, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant, posing a risk of serious and potentially irreversible hearing damage to Plaintiff and other consumers."), *id.* ¶ 238 (Tepezza "was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible hearing issues to Plaintiff and other consumers."); *id.* ¶ 239 (Tepezza "was defective in design or formulation in that its limited and unproven effectiveness and low efficacy did not outweigh the risks of serious and potentially irreversible hearing issues posed by the drug.").

Those allegations do not identify what aspect of Tepezza's design makes it defective. Nor do they offer facts from which the Court could reasonably infer some

possible design defect. Therefore, such allegations are insufficient to state a design defect claim under the federal pleading standard as applied to each of the relevant state laws. *See Marroquin v. Pfizer, Inc.*, 367 F. Supp. 3d 1152, 1164 (E.D. Cal. 2019) (applying California law, plaintiff must "identify what aspect of [the drug] makes it defective"); *Tsavaris v. Pfizer, Inc.*, No. 1:15-CV-21826-KMM, 2016 WL 375008, at *2 (S.D. Fla. Feb. 1, 2016) (applying Florida law, dismissing design defect claim where plaintiff "fail[ed] to plead any facts identifying [drug's] purported design defect" and "merely declare[d] [a drug] was unreasonably dangerous" and that "its risks exceeded any benefits or utility associated with the design or formulation"); *Kramer v. Ethicon, Inc.*, No. CV GLR-20-3747, 2021 WL 6135206, at *4 (D. Md. Dec. 28, 2021) (applying Maryland law, plaintiff must allege facts that show a "defect, attribution of the defect to the seller, and a causal relationship between the defect and the injury"); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) (applying New York law, plaintiff must "plead facts identifying [drug's] design defect," not "merely plead[] the legal conclusion that the [drug] was defective"); *Vicente v. DePuy Synthes Cos.*, 570 F. Supp. 3d 232, 242 (D.N.J. 2021) (applying New Jersey law, "a defect must be alleged factually"); *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 541–42 (E.D. Pa. 2021) (applying Pennsylvania law, dismissing negligent design claim where allegations failed to address the design of the device "in any level of meaningful detail"); *Maness v. Bos. Sci.*, 751 F. Supp. 2d 962, 968–69 (E.D. Tenn. 2010) (applying Tennessee law, holding that plaintiff must allege facts from which the court can infer the device was defective and the injuries were caused by the defective condition); *Cerveny v. Aventis,*

Inc., No. 2:14-cv-00545, 2015 WL 13640496, at *2 (D. Utah July 14, 2015) (applying Utah law, dismissing negligent design claim where plaintiffs "failed to plead sufficient facts to support" that fertility drug caused birth defects).

Plaintiffs argue that under Florida and New York law, they need not identify a design defect if a plaintiff would not possess the sort of technical information required to allege one before discovery. But they rely on cases where district courts applied the federal pleading standard to complaints with far more factual allegations than their complaints have. *Cf. Merino v. Ethicon Inc.*, 536 F. Supp. 3d 1271, 1281 (S.D. Fla. 2021) (alleging several defects in defendant's pelvic mesh products including "the use of polypropylene and collagen in the device; a risky implanting procedure; the difficulty in achieving the product's removal; and the tendency of the device to degrade, shrink, and fragment"); *Parillo v. Stryker Corp.*, No. 15-CV-155, 2015 WL 12748006, at *3 (N.D.N.Y. Sept. 29, 2015) (plaintiff alleged that "he received a medical diagnosis of hardware failure" and "a product defect was determined to be the cause of the hardware failure."); *Sullivan v. Aventis, Inc.*, No. 14-CV-2939-NSR, 2015 WL 4879112, at *1 (S.D.N.Y. Aug. 13, 2015) (plaintiff alleged that "due to an extended half-life, the medicine remained in her mother's system during the period of Plaintiff's organogenesis, causing Plaintiff's birth defects"). Certainly, Plaintiffs need not *prove* a specific defect in Tepezza's design at this stage. But they must do more than assert the conclusion that Tepezza is defectively designed. They must allege facts that "raise a right to relief above the speculative level." *See Twombly*, 550 U.S. at 555.

Plaintiffs further argue that they have identified a defect in Tepezza's design: that it was administered at "too high" of a dose. *E.g.*, R. 198 at 7 n.7, 12. There are no allegations in the complaints about what the standard dose of Tepezza is or what dosage of the drug each Plaintiff received. There is also no suggestion that there has been any change in the FDA-approved dosage since Tepezza's launch. Instead, Plaintiffs point to a single paragraph (repeated twice):

> Reasonable alternative designs existed, which could have minimized or eliminated the risk of hearing loss with Tepezza while maintaining any efficacy that could be obtained from using the drug. For example, studies have demonstrated that hearing-loss injuries can be minimized by using half the dose of Tepezza while also maintaining efficacy that can be obtained from the drug. Defendant knew or should have known, if it had properly tested the drug before introducing it into the marketplace, that such reasonable alternatives existed and could feasibly be implemented.

FAC ¶¶ 243, 255.

Yet this allegation is not well pled. Contrary to the allegation, Plaintiffs do not identify multiple "studies," but instead rely on a single case report from 2023, which states that "[t]o date, there are no dosing studies of [Tepezza] for TED." *See id.* ¶¶ 243 n.6, 255 n.7; R. 181-2 at 5; *see also Swiatek v. CVS Pharmacy, Inc.*, No. 23-CV-01523, 2024 WL 1328801, at *7 (N.D. Ill. Mar. 28, 2024) ("Plaintiff's allegation that the product increased 'the likelihood of demineralization, dental erosion, greater sensitivity, and higher incidences of dental caries' remains conclusory and not supported by the publications he references.").

At most, Plaintiffs allege (through incorporation by reference) the content of that report, which summarizes the case of a single patient with preexisting hearing loss who was treated twice with Tepezza. R. 181-2 at 1. After four infusions of Tepezza

(an initial infusion of 10 mg/kg followed by three infusions of 20 mg/kg), she showed reduced TED symptoms but worsening hearing loss and therefore discontinued treatment. *Id.* at 3. She "never fully recovered to her initial baseline" hearing. *Id.* One year later, she restarted Tepezza and after treatment with eight "half-dose" (10 mg/kg) infusions, showed "similar efficacy" in treating TED symptoms as the first course with "mild changes in hearing" that "did not meet the AHSA criteria for additional ototoxicity." *Id.* at 4. The authors stated, "[f]urther studies are needed to investigate optimal dosing of [Tepezza] for TED." *Id.*

This case report does not permit the reasonable inference that "using half the dose of Tepezza" is a feasible, safer alternative design. Plaintiffs define "half the dose" as either "[half] the number of doses administered or [half] the volume of Tepezza administered in each dose." *E.g.* R. 198 at 28, 32. The report does not support the former option as a safer alternative, as the patient experienced worsening hearing loss after four of the eight planned infusions. It is also inconsistent with another alleged case report of a patient who developed hearing-related symptoms after the third infusion of Tepezza. *See* FAC ¶ 115. The case report also does not plausibly support the latter option as a safer alternative. The patient—who had preexisting hearing loss—still experienced hearing-related symptoms during the half-volume course of Tepezza. And there are any number of reasons unrelated to the volume of Tepezza per infusion that this patient's hearing loss did not worsen by the same magnitude during the second course of treatment as it did during the first. Most obviously, by the time she started the half-volume course of Tepezza, her hearing had

not returned to her pre-treatment baseline. Viewed alongside the fact that there were no dosing studies as of last year, this case report does not "raise a reasonable expectation that discovery will reveal evidence" that Tepezza's dosage rendered its design defective. *Twombly*, 550 U.S. at 545.

Notably, Plaintiffs do not contend Tepezza's design is defective because it is an IGF-1R inhibitor. R. 198 at 14 n.7. However, Plaintiffs appear to argue that Tepezza's dose "excessively inhibits" IGF-1R. *See* R. 198 at 20.[8] The Court cannot make that inferential leap based on the allegations in the complaints. Plaintiffs merely allege that Tepezza is an IGF-1R inhibitor, and that IGF-1 "deficiencies result in hearing loss." FAC ¶¶ 42, 46, 103, 104. There are no allegations connecting these facts to dosage or bioavailability. Nor do those facts reasonably suggest that higher doses of an IGF-1R inhibitor cause hearing loss while lower doses do not, particularly where Plaintiffs allege that "[i]nhibition of IGF-1R" is a "mechanism for Tepezza-induced ototoxicity." *Id.* ¶ 106.

The parties disagree as to which state laws require the allegation of a feasible, safer alternative to state a design defect claim. However, Plaintiffs point to no other facts beyond the allegation of a half-dose alternative to support their claim that Tepezza's design is defective. R. 198 at 9 ("By alleging that a half-dose is a safer alternative, each Plaintiff has alleged design defect with sufficient specificity.").

[8] Plaintiffs separately state, "Because a half dose of Tepezza significantly reduces the amount of IGF-1 inhibitor in the body, such a design—or any design that minimizes the dose of the drug or increases its bioavailability—would minimize the levels of IGF-1." R. 198 at 9. Though unclear, the Court assumes Plaintiffs mean to argue that reducing the amount of IGF-1 inhibitor would *increase* the levels of IGF-1.

Accordingly, because Plaintiffs do not plausibly allege a half-dose regime as a safer alternative, the Court finds that Plaintiffs' allegation that Tepezza is defectively designed remains conclusory and speculative.

Plaintiffs lastly request the opportunity to amend their complaints. They do not claim to have to have discovered additional information supporting dosage as the defect in Tepezza's design or a half-dose regime as a safer alternative. Instead, Plaintiffs say that since filing the operative complaints, they "learned that Defendant's parent corporation is actively recruiting for a Phase 3 clinical trial on a subcutaneous delivery method for [Tepezza], which represents another potential safer alternative design that Plaintiffs could plausibly allege." R. 198 at 9.

The deadline for amending the complaints was March 1, 2024. Where a party seeks leave to amend its complaint after the scheduling order's deadline for amending pleadings has passed, the Court applies the heightened good-cause standard of Rule 16(b)(4) before considering whether the requirements of Rule 15(a)(2) are satisfied. *Bell v. Taylor*, 827 F.3d 699, 706 (7th Cir. 2016) (cleaned up). "In making a Rule 16(b) good-cause determination, the primary consideration for district courts is the diligence of the party seeking amendment." *Alioto v. Town of Lisbon*, 651 F.3d 715, 720 (7th Cir. 2011).

Horizon points out that this clinical trial was posted on ClinicalTrials.gov on January 31, 2024, nearly one month before Plaintiffs filed their FACs and the deadline to amend. In other words, Plaintiffs had every opportunity to allege facts about this clinical trial before the deadline for amendment. *See Bell*, 827 F.3d at 706

(affirming denial of motion to amend eight months after deadline where plaintiff knew or should have known the facts underlying the amendment). Plaintiffs have not shown good cause for the amendment they propose. Horizon also notes that the clinical trial is not scheduled to be completed until March 2, 2026, and there have been no efficacy or safety results published thus far. The mere initiation of a study that explores a potential new delivery method, without any results, does not plausibly suggest that the current delivery method is the defective aspect of Tepezza or that the new delivery method is equally efficacious and safer than the present delivery method. Thus, even if Plaintiffs showed good cause for the proposed amendment, it would be futile. For those reasons, Plaintiffs' design defect claims are dismissed with prejudice.

III. Fraudulent Misrepresentation

Plaintiffs Chryssos, Egger, Ford, Meyers, and Stern bring fraudulent misrepresentation claims under California, New York, Pennsylvania, and Utah law. Horizon moves to dismiss for failure to state a claim.

A. Legal Standard

A party alleging fraud or mistake "must state with particularity the circumstances constituting [the] fraud or mistake." Fed. R. Civ. P. 9(b). To meet this particularity requirement, "a plaintiff ordinarily must describe the 'who, what, when, where, and how' of the fraud." *Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 441–42 (7th Cir. 2011) (quoting *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009)). But the Seventh

Circuit has "warned that courts and litigants often erroneously take an overly rigid view of the formulation." *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 737 (7th Cir. 2014). "The precise level of particularity required under Rule 9(b) depends upon the facts of the case[.]" *Id.* At bottom, to satisfy the Rule 9(b) particularity standard, "[i]t is enough to show, in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy." *Rolls-Royce*, 570 F.3d at 854–55 (citations omitted).

B. Application

To state a fraudulent misrepresentation claim under the relevant state laws, a plaintiff must allege "(1) a material misrepresentation or omission of fact; (2) which the defendant knew to be false; (3) which the defendant made with the intent to defraud; (4) upon which the plaintiff reasonably relied; and (5) which caused injury to the plaintiff." *Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, 783 F.3d 395, 402 (2d Cir. 2015); *see also State v. Apotex Corp.*, 282 P.3d 66, 80 (Utah 2012); *Martin v. Lancaster Battery Co.*, 530 Pa. 11, 19 (Pa. 1992); *Robinson Helicopter Co. v. Dana Corp.*, 34 Cal. 4th 979, 990 (Cal. 2004).

Horizon argues that the complaints fail to set forth the "who, what, when, where, and how" of any misrepresentations or omissions as required by Rule 9(b). Plaintiffs' fraudulent misrepresentation claims "center" on the pre-July 2023 label. R. 197 at 8.[9] Plaintiffs contend that their complaints allege two affirmative

[9] Plaintiffs say their fraudulent misrepresentation claims are focused on the label. Yet the complaints also allege that Horizon made misrepresentations or omissions

misrepresentations with particularity: (1) that Horizon "overstated the efficacy of Tepezza" and (2) "Horizon claimed that hearing impairment would affect just 10% of patients when it knew as many as 40% potentially faced hearing impairment." *Id.* at 12.

The former is not pled with sufficient specificity. Plaintiffs do not point to any particular statement in the label regarding the efficacy of Tepezza or explain how the label misrepresented the efficacy of the drug. Instead, Plaintiffs' allegations regarding efficacy are highly generalized. *See, e.g.*, FAC ¶ 259 ("Defendant's fraudulent, intentional and material misrepresentations and omissions regarding the safety and efficacy of Tepezza and of Tepezza's side effects, including an increased risk for permanent hearing loss, tinnitus, and related sequelae were communicated to Plaintiff directly through promotional materials, advertising, product inserts, and the product monograph with the intent that Plaintiff use Tepezza."); *id.* ¶ 277 ("Defendant fraudulently and intentionally misrepresented the safety and efficacy of Tepezza in its labeling, advertising, product inserts, promotional materials, or other marketing resources and materials."); *id.* ¶ 279 ("Defendant overstated the benefits and safety of Tepezza[.]"). Such allegations are insufficiently particular to satisfy Rule 9(b).

"in its . . . advertising, . . . promotional materials, or other marketing resources and materials." FAC ¶ 277. Plaintiffs do not identify any particular advertisements or promotional materials, nor do they identify any particular misstatement or omission in those materials. Thus, to the extent Plaintiffs seek to assert fraudulent misrepresentation claims based on sources other than the label, such allegations fall short of Rule 9(b)'s particularity requirement.

The latter suffers from a different pleading defect. On the one hand, Plaintiffs allege that the information in the Adverse Reactions section of the label is "false" because it "indicate[s] that [hearing loss and tinnitus] occurred in less than 10% of clinical trial patients" even though "these conditions occurred in as many as 40% of clinical trial patients receiving Tepezza." FAC ¶ 267. Yet, other allegations confirm that the 10% rate was an accurate count of the number of participants in the two clinical studies referenced in that section of the label. *See, e.g.*, FAC ¶ 67 (The Phase 2 and 3 Acute TED studies were provided to the FDA to seek initial approval. Those studies indicated that hearing impairment was a side effect that occurred in about 10% of patients. And that 10% figure appears on the label."). So, Plaintiffs' assertion of falsity is not well pled.

Plaintiffs' fraudulent misrepresentation claims are really about what Horizon failed to include on the label. Plaintiffs allege that Horizon knew but omitted that Study 401 indicated a higher incidence rate than that observed in the clinical trials from the label from January 2020 to present. *Id.* ¶¶ 67, 263–67. And Plaintiffs allege that Horizon omitted the known risk of permanent hearing loss and tinnitus from the label prior to July 2023. *Id.* ¶¶ 98, 118, 125, 132, 140, 175, 259, 268–70, 272. Such allegations are sufficient to plead the "who, what, when, where, and how" of a fraudulent misrepresentation claim as required by Rule 9(b). *See Smith v. Boehringer Ingelheim Pharms., Inc.*, 886 F. Supp. 2d 911, 927 (S.D. Ill. 2012) (denying motion to dismiss fraud claims against manufacturer where plaintiff alleged misrepresentations in drug's labeling and prescribing information); *see also In re*

Zofran (Ondansetron) Prods. Liab. Litig., No. 1:15-MD-2657-FDS, 2017 WL 1458193, at *7 (D. Mass. Apr. 24, 2017) (denying motion to dismiss claim that manufacturer fraudulently misrepresented the safety of ingesting Zofran during pregnancy on its labeling where complaint was "sufficiently specific as to the time, place, and content of the alleged false representation").

Horizon argues that Plaintiffs cannot rely on omissions because they do not allege that Horizon had a duty to disclose the omitted information. But the complaints allege that Horizon had a duty to warn Plaintiffs, their physicians, and other consumers about Tepezza's dangers and side effects—including permanent hearing loss and tinnitus—on the label. *E.g.*, FAC ¶¶ 159, 209, 219, 276. It is not clear whether Horizon intends to argue that there is no such duty under the applicable state laws. Horizon does not cite authority to support that proposition. Instead, Horizon relies exclusively on cases outside of the prescription drug context that discuss the duty to disclose under Illinois law, which does not apply to any of the complaints at issue. The allegations in the complaints are sufficient to plead that Horizon owed Plaintiffs a duty to disclose the omitted dangers and side effects of Tepezza on the label.

Horizon also argues that Plaintiffs do not sufficiently plead the "who" because they do not identify the specific employees at Horizon who made the omissions. Courts in this District have taken different approaches to the "who" requirement in the pharmaceutical context. *Compare In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2014 WL 7365872, at *6 (N.D. Ill. Dec. 23, 2014)

("Plaintiffs have stated the 'who': they contend that defendants misrepresented the safety and approved uses of TRTs in communications directed at plaintiffs and their physicians.") *with Cardenas v. Abbott Laby's*, No. 11 C 4860, 2011 WL 4808166, at *5 (N.D. Ill. Oct. 7, 2011) (holding plaintiffs did not adequately plead the "who" where they alleged "Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible" fraudulently represented that a drug was safe). Ultimately, the level of specificity required depends upon the circumstances of each case. *See Pirelli*, 631 F.3d at 442 ("[B]ecause courts and litigants often erroneously take an overly rigid view of the ["who, what, when, where, and how"] formulation, we have also observed that the requisite information . . . may vary on the facts of a given case."). In this case, it is unreasonable to expect Plaintiffs to know or even discover in a pre-suit investigation the names of the individual employees who were responsible for the content of Tepezza's label. *Cf. Biesterfeld v. Ariosa Diagnostics, Inc.*, No. 1:21-CV-03085, 2022 WL 972281, at *5 (N.D. Ill. Mar. 31, 2022) ("[T]his is not the type of fraud case in which the Plaintiffs can be expected to identify the names of the [Defendant's] employees . . . who wrote the statements at issue.").

Horizon further argues that Plaintiffs do not plead their injuries with sufficient detail. Rule 9(b) does not require that Plaintiffs plead their injuries or damages with particularity. *See Native Am. Arts, Inc. v. Duck House, Inc.*, No. 05 C 2176, 2007 WL 8045973, at *3 (N.D. Ill. Mar. 1, 2007). But even if it did, Plaintiffs provide more than enough detail. Plaintiffs do not simply state that taking Tepezza injured them. They

allege that "Tepezza injured [them] by causing permanent hearing damage" and that they "now suffer[] from permanent hearing loss and/or tinnitus as a result of [their] infusions with Tepezza." FAC ¶ 11. Plaintiffs also allege that had they and their healthcare providers relied on the omissions and that they would not have used Tepezza, or their providers would not have prescribed them Tepezza, had they known the truth about the risks of taking the drug. *Id.* ¶¶ 278, 279. In other words, Plaintiffs specify what type of injuries they suffered and causally connect those injuries to the omissions they relied upon. Neither Rule 8 nor Rule 9(b) requires more.

However, Horizon raises one final issue on which the Court cannot rule without further briefing. Horizon argues that because the fraudulent misrepresentation claims center on the FDA-approved label, those claims are essentially "fraud-on-the-FDA" claims which are preempted by *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Though Horizon raises this argument briefly in its opening brief, Horizon develops the argument in its reply. Likewise, while Plaintiffs previously addressed *Buckman* preemption generally in a response to the motion to dismiss Williams' complaint, see R. 26 at 6–9, Williams did not assert a fraudulent misrepresentation claim, nor was Plaintiffs' argument in that surreply directly responsive to Horizon's argument in the instant briefing. Notably, Plaintiffs did not address the Seventh Circuit precedent referenced in Horizon's reply.

Because both the failure-to-warn and fraudulent misrepresentation claims are focused on the label, it is not likely that dismissing the fraudulent misrepresentation claims as preempted by *Buckman* would affect the scope of discovery moving forward.

Accordingly, the Court is inclined to ask the parties to fully brief the issue at summary judgment. However, if the parties believe that it is important for the Court to address *Buckman* preemption at this stage, the Court will require a surreply from Plaintiffs and a sur-surreply from Horizon in order to give fair consideration to the issue.

Lastly, regardless of *Buckman*, Ford's fraudulent misrepresentation claim requires dismissal for another reason. As Horizon points out, Pennsylvania law does not recognize fraudulent misrepresentation claims that rest on a failure-to-warn theory. R. 184 at 13 n.10; *see Kline v. Pfizer*, No. 08-3238, 2009 WL 32477, at *2–4 (E.D. Pa. Jan. 6, 2009) (plaintiff's fraudulent misrepresentation claim was barred under Pennsylvania law where "[t]he very basis of these claims is that [defendant] knew of the dangers associated with [the drug] but fraudulently concealed this knowledge and fraudulently misrepresented that the drug was safe by failing to warn of its dangers"); *see also Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996). Plaintiffs do not offer any argument in response, which constitutes a waiver. *See Refined Metals Corp. v. NL Indus. Inc.*, 937 F.3d 928, 935 (7th Cir. 2019). But even without a waiver, the cited authority demands the dismissal of Ford's fraudulent misrepresentation claim with prejudice.

IV. Kanesta-Rychner Leave to Amend

Kanesta-Rychner requests leave to file a second amended complaint. Her original complaint included claims for negligent failure to warn and negligent design defect, but she inadvertently omitted those claims from her first amended complaint.

As previously discussed, where a party seeks to amend a complaint after the deadline for amendments to pleadings has passed, the Court first considers whether the party seeking amendment has shown good cause, which centers on that party's diligence. *Alioto*, 651 F.3d at 719. If good cause is shown, the Court considers whether the party seeking amendment satisfies the requirements of Rule 15(a)(2). *Id.*

Kanesta-Rychner does not clear the first hurdle. She did not seek leave to amend until seven months after the March 1, 2024 deadline for amendments. She claims that she did not realize the omission until July 19, 2024, when Horizon filed its motion to dismiss the design defect claims, which noted that Kanesta-Rychner did not allege any such claims. But that "explanation does not pass muster." *See id.* (plaintiff's claim that he had no reason to know his complaint was deficient until the defendants filed their motion to dismiss did not establish good cause for late amendment); *see also Freeman v. Ocwen Loan Servicing, LLC*, 113 F.4th 701, 708 (7th Cir. 2024) (same). What's more Kanesta-Rychner waited two-and-a-half months after Horizon filed the motion to dismiss to seek amendment. Such conduct falls short of the diligence required to show good cause. *See Alioto*, 651 F.3d at 720 (finding plaintiff "acted with insufficient diligence" not merely because he waited to seek leave to amend for eight months beyond the court's deadline but also because he waited more than two months after receiving the motion to dismiss).[10]

[10] It bears noting that Kanesta-Rychner had reason to know about the missing claims even before the motions to dismiss. On June 11, 2024, Horizon notified Kanesta-Rychner via email that her strict liability design defect claim was not viable. Kanesta-Rychner agreed and voluntarily dismissed that claim on July 16, 2024. Counsel must

Kanesta-Rychner does not attempt to distinguish her case from Seventh Circuit precedent. Instead, she urges the Court to set aside her lack of diligence and consider instead the posture of this case and whether permitting an amendment would prejudice Horizon. Yet, she relies on cases from outside the Seventh Circuit. The precedent in this Circuit is clear. "The central consideration in assessing whether good cause exists is the diligence of the party seeking to amend." *Allen v. Brown Advisory, LLC*, 41 F.4th 843, 852–53 (7th Cir. 2022). And here, diligence was lacking.

The single case she cites from this Circuit, *Woodson v. 3M Co.*, No. 3:21-cv-50244, 2022 WL 1450385, at *2 (N.D. Ill. May 9, 2022), is inapposite. There, the district court granted leave for a late amendment because the plaintiff did not learn of the facts relevant to new claims until after the deadline for amendment due to the defendant's delay in producing certain documents. *Id.* at *3–4. In contrast, Kanesta-Rychner had all the information needed to add back in the missing claims before the deadline. *See Bell*, 827 F.3d at 706 (affirming denial of motion to amend eight months after deadline where plaintiff knew or should have known the facts underlying the amendment).

Because Kanesta-Rychner cannot establish good cause for her late amendment, the Court denies her motion without reaching the parties' arguments under Rule 15. That said, it is not clear that she needs to amend her complaint in order to assert her failure-to-warn claim under a negligence theory. *See Koger v. Dart*,

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have reviewed the first amended complaint during that discussion or upon filing her notice of dismissal. That counsel did not take stock of the remaining claims in the first amended complaint at that time shows insufficient diligence.

950 F.3d 971, 974 (7th Cir. 2020) ("[T]he fact that the complaint omits a legal theory cannot block a plaintiff from invoking that theory."). Kanesta-Rychner does not raise this argument, nor do the parties discuss the relevant precedent. Accordingly, if Kanesta-Rychner later seeks to invoke theories of liability that are not spelled out in her complaint, and Horizon contests that effort, the Court will require further briefing.

Conclusion

For the foregoing reasons, the Court denies the motion to dismiss the failure-to-warn claims [177]; grants the motion to dismiss the design defect claims [180]; grants in part, denies in part, and continues in part the motion to dismiss the fraudulent misrepresentation claims [183]; and denies Plaintiff Kanesta-Rychner's motion for leave to file a second amended complaint [230].

ENTERED:

Thomas M Durkin

Honorable Thomas M. Durkin
United States District Judge

Dated: January 10, 2025